

## **British Paediatric Surveillance Unit (BPSU) study - Fetal Alcohol Syndrome**

Surveillance of Fetal Alcohol Syndrome (FAS) commenced in October 2018. The study aims to determine the incidence of FAS in the UK and Ireland; investigate which services are accessed by babies and children affected by the condition; and raise awareness about FAS among clinical practitioners.

This study is not investigating Fetal Alcohol Spectrum Disorder.

### **Lead investigator**

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### **About the study**

#### **Overview**

Fetal Alcohol Syndrome (sometimes known as FAS) is a rare condition which occurs when the developing baby is exposed to alcohol in the womb. Alcohol can cross the placenta into an unborn baby's blood stream.

The exposure of an unborn baby to alcohol can then affect the development of the brain, leading to challenges in learning and development. Alcohol can also affect the development of other parts of the unborn baby's body, particularly the face. The exact amount of alcohol that cause FAS is unknown but FAS can be completely prevented by avoiding the use of alcohol in pregnancy.

In addition to the specific effects on growth, brain and facial development, babies and children affected by FAS can sometimes have:

- hearing problems
- speech problems
- seizures (fits)
- liver problems
- kidney problems
- heart defects.

In the UK and Ireland we currently know little about the exact numbers of babies and children affected by FAS and the services they require to support them throughout their childhood. The aim of the study is to answer both these questions and ultimately improve the treatment and support we can provide to babies, children and families affected by FAS.

This study is not investigating the wider condition known as Fetal Alcohol Spectrum Disorder (FASD). FASD is an umbrella term for several diagnosis that are all related to prenatal exposure to alcohol. These are: Fetal Alcohol Syndrome (FAS); Partial Fetal Alcohol Syndrome (PFAS); Alcohol Related Neuro-developmental Disorder (ARND); and Alcohol Related Birth Defects (ARBD).

### **Case definition**

Any child < 16 years old newly diagnosed with FAS in the last month based on the presence of all three of the following clinical features:

#### **1. Facial features**

- Smooth philtrum
- Thin upper lip
- Short palpebral fissures

#### **2. Poor growth**

- In utero < 10th centile for gestational age
- Postnatal - FTT

#### **3. Structural or functional brain abnormality**

- Head circumference < 10th centile or microcephaly with increasing age
- Abnormal brain scan
- Developmental delay / learning difficulties
- Abnormal neurological signs

A history of maternal alcohol use during pregnancy is not required for reporting and cases may be reported if this is uncertain or unknown.

We will provide clinicians with a leaflet defining these characteristics at study start and also make this available as an appendix within the questionnaire. This information will not be amended during the case-reporting period.

## **Reporting instructions**

Please report any cases of babies or children under 16 years of age meeting the surveillance case definition of FAS whom you have seen in the last month.

## **Duration**

October 2018 to October 2019

## **How will the information be collected?**

Medical doctors across the UK and the Republic of Ireland will fill in a questionnaire for any child or baby under 16 years of age.

The questionnaire will ask clinical information about the case of FAS. This information will be sent onto the study team in Leeds who will then look at the findings. The results will be presented in medical journals and scientific conferences.

## **How the research team use the information?**

By collecting patient information it is hoped that the investigators will increase our understanding about FAS among children and babies in the UK and Republic of Ireland. This may help us to improve our understanding of the current problems associated with this condition. This will help shape future approaches to preventing and managing the condition. Improved knowledge will allow better planning and delivery of specialised services.

All data collected will be held securely and confidentiality maintained at all times. BPSU researchers do not contact families or children who have FAS.

Leeds Teaching Hospitals NHS Trust (LTHNT) is the sponsor for this study based in the UK. They will be using information from case medical records to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after patient information and using it properly. Identifiable clinical information including age in months (taken from date of birth), sex and ethnicity are retained securely five years as a paper record and then electronically for 20 years, by LTHNT.

Rights to access, change or move your patient information are limited, as the investigator needs to manage patient information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, they will keep the information about you that the investigator has already obtained. To safeguard your rights, they will use the minimum personally-identifiable information possible.

You can find out more about the study group use your information by contacting Dr Kathryn Johnson, principal investigator.

## **Funding**

This study is being funded by the Sir Halley Stewart Trust with matched funding from Public Health England.

## **Approval**

This study has been approved by London - Camden & Kings Cross Research Ethics Committee (REC reference: 17/LO/1020; IRAS project ID: 212510); HRA Confidentiality Advisory Group (reference: 17/CAG/0161); and the Scottish Public Benefit and Privacy Panel (1718-0262).

## **Support group**

<http://www.nofas-uk.org/>